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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,367	06/02/2006	Luca Rampoldi	291385US0PCT	3683

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EXAMINER	
SULLIVAN, DANIELLE D	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
07/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/581,367	RAMPOLDI ET AL.	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *4* is/are allowed.

6)☒ Claim(s) *1-3 and 5-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/29/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Withdrawn rejections

Applicant's amendments and arguments filed 3/25/2010 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below are herein withdrawn.

Response to Arguments

Applicant's arguments, filed 3/25/2010, with respect to the rejection(s) of claim(s) 1-18 under Spireas (2002/0091159) have been fully considered and are persuasive because PEG 400 does not have the specified melting point as discussed in the interview March 3,2010. Therefore, the rejections have been withdrawn.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7, 8, 12, 13, 15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruna et al. (US6,488,964).

Bruna et al. discloses a tablet comprising 43% gabapentin and 1.7% PEG 6000 (Example 2). This reads on a gabapentin granulate comprising polyethylene glycol having a melting point of 50-80 degrees Celsius.

Claims 1, 5, 7, 8, 9, 12, 13, 15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Berner et al. (WO 03/035040).

Berner et al. discloses tablets comprising 60% gabapentin and 0-39% PolyOx Coagulant, NF (Example 1). Tablets comprising 50% gabapentin and 24.5% PolyOx Coagulant, NF are also exemplified (Example 2). Berner et al. also disclose tablets comprising 44.76% gabapentin and 21.99% PolyOx WSR Coagulate, NF and tablets comprising 61.11% gabapentin, 27.09% PolyOx WSR 303, NF and 11.8% additives (Example 3). This reads on a gabapentin granulate comprising polyethylene glycol having a melting point of 50-80 degrees Celsius.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3, 6, 10, 11,14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berner et al. (WO 03/035040).

Applicant's Invention

Applicant claims a gabapentin granulate comprising gabapentin and polyethylene glycol having a melting point between 50-80 degrees Celsius. Claim 2 limits the gabapentin to being present in an amount higher than 80% by weight of the granulate. Claim 3 limits the gabapentin to being present in an amount higher than 90% by weight of the granulate. Claims 6, 10, 11 and 16 limit the composition to a capsule form obtained by filling a gelatin capsule with the granulate. Claim 14 limits the composition to one comprising 70-98% gabapentin, 2-25% polyethylene glycol and 0-20% additives.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Berner et al. teaches the compositions disclosed in the above 102(b) rejections. Additionally, Berner et al. teach that in order to provide for sustained delivery it is preferable that at least 40wt% of gabapentin is retained in the dosage form after 1 hour. However, it may be desired to utilize a dosage form that provides for substantially all of the gabapentin to be delivered over the intended duration, where substantially all is taken to mean at least about 85% (page 8, lines 18-25). The dosage forms may be formulated as solids or capsules wherein the amount of active agent is 0.1-95% (page 10, lines 17-23). Hard or soft gelatin capsules which contain the granulates may be used which allows for the granulate to be formulated for controlled release in a gastric retained dosage form (page 11, lines 5-8; page 10, lines 12-19).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Berner et al. do not exemplify gelatin capsules, however, placing the granulates into gelatin capsules is taught (page 11, lines 5-8; page 10, lines 12-19). Berner et al. fail to exemplify compositions with higher than 80 or 90% by weight of granulate, however, formulating solids or capsules with 0.1-95% of gabapentin is taught (page 10, lines 17-23). Berner et al. do not provide any examples where the composition comprises 70-98% gabapentin, 2-25% polyethylene glycol and 0-20% additives. However, Example 3 comprises 61.11% gabapentin, 27.09% PolyOx WSR 303 (polyethylene glycol), NF and 11.8% additives, and adjusting the amount of gabapentin to 70-95% would have been within the skill of one ordinary in the art because Berner et al. teach that it may be desired to utilize a dosage form that provides for substantially all of the gabapentin to be delivered. Substantially all is taken to mean at least about 85%.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention utilize the teachings of Berner et al. to further include formulating capsules and a compositions comprising 70-98% gabapentin, 2-25% polyethylene glycol and 0-20% additives. First, one would have been motivated to formulate the granulates into capsules because Berner et al. teach that capsules allow for the granulate to be formulated for controlled release in a gastric retained dosage form which would protect the drug from gastric juices.

Furthermore, one would have been motivated to manipulate ranges during routine experimentation to formulate compositions comprising 70-98% gabapentin, 2-25% polyethylene glycol and 0-20% additives. Berner teaches that the concentration of gabapentin can range from 0.1-95% of the formulation and it may be desired to utilize a dosage form that provides for substantially all of the gabapentin to be delivered.

Allowable Subject Matter

Claim 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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